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| APPLICATION NO.             | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|-----------------------------|----------------|----------------------|-------------------------|------------------|--|
| 09/165,546                  | 10/02/1998     | KNUTH ALEXANDER      | LUD5466.4-JE            | 8012             |  |
| 24972 7                     | 590 03/25/2003 |                      |                         |                  |  |
| FULBRIGHT & JAWORSKI, LLP   |                | •                    | EXAMINER                |                  |  |
| 666 FIFTH AV<br>NEW YORK, I |                |                      | DECLOUX, AMY M          |                  |  |
|                             |                |                      | ART UNIT                | PAPER NUMBER     |  |
|                             |                |                      | 1644                    | 111              |  |
|                             |                |                      | DATE MAILED: 03/25/2003 | <b>U</b> b       |  |
|                             |                |                      |                         |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Applicati n No.   | Applicant(s)   |  |  |  |
|--|---|--|--|--|--|
|  | 09/165,546  | ALEXANDER ET AL.   |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |
|  | Amy M. DeCloux  | 1644   |  |  |  |
| The MAILING DATE of this communicate Period for Reply  | tion appears on the cover sheet wit   | th the corresp ndence address  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNICA  - Extensions of time may be available under the provisions of 3' after SIX (6) MONTHS from the mailing date of this communic  - If the period for reply specified above is less than thirty (30) da  - If NO period for reply is specified above, the maximum statuto  - Failure to reply within the set or extended period for reply will,  - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).  Status | TION. 7 CFR 1.136(a). In no event, however, may a reation. ays, are reply within the statutory minimum of thirty period will apply and will expire SIX (6) MON' by statute, cause the application to become AB. | eply be timely filed  (30) days will be considered timely.  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133). |  |  |  |
| 1) Responsive to communication(s) filed  | on <u>21 February 2003 and 27 Dec</u>   | <u>ember 2002</u> .  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b)  | ☐ This action is non-final.   |  |  |  |  |
| Since this application is in condition fo closed in accordance with the practice Disposition of Claims   |   |  |  |  |  |
| 4)⊠ Claim(s) <u>84 and 88-95</u> is/are pending i  | n the application.  |  |  |  |  |
| 4a) Of the above claim(s) is/are v   | withdrawn from consideration.   |  |  |  |  |
| 5)⊠ Claim(s) <u>84 and 88-95</u> is/are allowed.   |   |  |  |  |  |
| 6) Claim(s) is/are rejected.   |   |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |  |  |  |  |
| 8) Claim(s) are subject to restriction   | n and/or election requirement.  |  |  |  |  |
| Application Papers   |   |  |  |  |  |
| 9) The specification is objected to by the E   | •   |  |  |  |  |
| 10) The drawing(s) filed on is/are: a)   |   |  |  |  |  |
| Applicant may not request that any objecti   |   |  |  |  |  |
| 11) The proposed drawing correction filed or   |   | isapproved by the Examiner.  |  |  |  |
| If approved, corrected drawings are requir   | • •   |  |  |  |  |
| 12) The oath or declaration is objected to by  | the Examiner.   |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |   |  |  |  |  |
| 13) Acknowledgment is made of a claim for  | r foreign priority under 35 U.S.C. §  | § 119(a)-(d) or (f).   |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |  |  |  |  |
| 1. Certified copies of the priority do   |   |  |  |  |  |
|  | cuments have been received in A   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |
| 14) Acknowledgment is made of a claim for o  | •   |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  |   |  |  |  |  |
| 15) Acknowledgment is made of a claim for  | domestic priority under 35 U.S.C.   | 99 120 and/or 121.   |  |  |  |
| Attachment(s)  | <b>,</b> □  | Discount (DTO 442) Discount No.(5)   |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO 3)</li> <li>Information Disclosure Statement(s) (PTO-1449) Pape</li> </ol>  | -948) 5) 🔲 Notice of I  | Summary (PTO-413) Paper No(s)  nformal Patent Application (PTO-152)  e Continuation Sheet .  |  |  |  |

Continuation of Attachment(s) 6). Other: Notice to Comply with Requirements for Sequence Disclosures.

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### **DETAILED ACTION**

Applicant's response filed 2-21-03, Paper No.44, is acknowledged. Applicant's After-final amendment, filed 12-27-02, Paper No. 42, has been entered.

This application is in condition for allowance except for the following formal matters:

## Specification

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the amino acid sequences disclosed in the Table on page 26 of the specification lack SEQ ID NO: tags. It is noted that page 25 of the specification discloses that said table the positions on SEQ ID NO:1 are given for each of the peptides. However it is noted that SEQ ID NO:1 is a nucleic acid molecule, and the referred to positions are based on a protein sequence. Further it is noted that the sequence listing does not contain a separate SEQ ID NO: tag for the amino acid sequence of the protein encoded by SEQ ID NO:1. One option for Applicant is to submit a sequence listing that contains a separate SEQ ID NO: tag for the amino acid sequence of the protein encoded by SEQ ID NO:1.

Applicants are required to resubmit a substitute disk and paper copy of the sequences according to the attached "Notice to Comply with the Sequence Rules." Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

#### Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

A. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically, Non-initialed and/or non-dated alterations have been made to citizenship of Inventor Gure.

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B. As outlined in Paper No. 9, mailed 5-22-01, the filing date of the parent application Serial number 09/062,422 is incorrect.

C. The declaration does not list the date that the instant application was filed on, nor the serial number.

## Allowable Subject Matter

Claims 84 and 89-95 are allowed.

Prosecution on the merits is closed in accordance with the practice under Ex parte Ouayle, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D. Patent Examiner, March 21, 2003 Patrick J. Nolan, Ph.D.
Primary Patent Examiner
Group 1640

# Application No.: 09/165,546 NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

| X           | <ol> <li>This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's<br/>attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR<br/>18230, May 1, 1990.</li> </ol>  |
|-------------|--|
|             | 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).  |
|             | 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).  |
|             | 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."            |
|             | <ol> <li>The computer readable form that has been filed with this application has been found to be damaged<br/>and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute<br/>computer readable form must be submitted as required by 37 C.F.R. 1.825(d).</li> </ol> |
|             | 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).   |
| X           | 7. Other: The Table on Page 26 of the specification discloses sequences which lack SEQ ID NO: tags. See attached Office Action.  |
| <b>Ap</b> r | plicant Must Provide: ${\sf ONLY}$ if the CRF/PAPR COPY SEQUENCE LISTING DOES NOT CONTAIN D SEQUENCEs.   |
| X           | An initial or <u>substitute</u> computer readable form (CRF) copy of the "Sequence Listing".   |
| X           | An <u>i</u> nitial or <u>substitute</u> paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.  |
| X           | A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).   |
| For         | questions regarding compliance to these requirements, please contact:  |
| For<br>For  | Rules Interpretation, call (703) 308-4216 CRF Submission Help, call (703) 308-4212 tentIn Software Program Support (SIRA) Technical Assistance   |
|             | To Purchase Patentin Software 703 206 2600   |

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